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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/681,473 | 10/08/2003 | Missoum Moumene | DEP 5169 | 7470 |
| 27777 | 7590 | 11/30/2005 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | REIMERS, ANNETTE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/681,473

Applicant(s)

MOUMENE ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-13 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

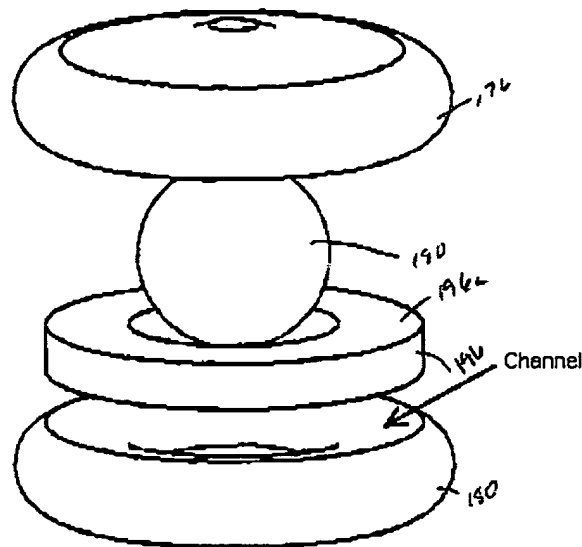
Claims 1-2, 6-8, 10, 12-13, 17 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Songer et al. (U.S. Patent Publication Number 2003/0220691).

Songer et al. disclose a motion disc capable of maintaining intervertebral spacing and comprising a first and second prosthetic vertebral endplate, 176 and 180, respectively, made of a non-metallic or polymer composite material, a first and second outer surface, adapted to mate with the first and second vertebral body, 191, a first inner surface comprising a first peripheral surface, a second inner surface comprising a second peripheral surface, a first and second convex articulation surface, and a body portion connecting the first and second inner and outer surfaces (see Figures 11E-11H and paragraph 0061, lines 4-13). In addition, the body portion of each endplate comprises a posterior and an anterior portion wherein the anterior portion can be thicker or equal in thickness to the posterior portion (see Figures 11G and 11H).

The motion disc also includes an articulating core member, 180, consisting of polyethylene or metal, comprising a first articulation surface adapted for articulation with the first articulation of the first endplate and a second articulation surface adapted for articulation with the first articulation surface of the second endplate (see Figures 11E-11F and paragraph 0007, lines 1-6).

Furthermore, the motion disc includes a peripheral elastomeric shock-absorbing component, 196, comprising a first surface, 196a, contacting and attached to the first peripheral surface of the first endplate, and a second surface, 196b, contacting and attached to the second peripheral surface of the second endplate. Moreover, each peripheral surface of the shock-absorbing component is capable of being tenaciously attached to the respective inner surface of each plate (see Figures 11E-11F and paragraph 0062, particularly lines 4-7).

The inner surface of each opposed endplate comprises a channel, wherein each peripheral surface of the shock-absorbing component is adapted to fit within the respective channel (see Figure 11F below). Songer et al. teaches the use of a sheath adapted to enclose the articulation surfaces and a lubricant disposed on the first articulation surface (see paragraph 0012, lines 5-10).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Songer et al. (U.S. Patent Publication Number 2003/0220691).

Songer et al. disclose the claimed invention except for the endplates being made of PEEK. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Songer et al. with a first and second endplate being made of PEEK-carbon fiber composite material, since it has been held to be within the general skill of a worker in the art to select a known material on the

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basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Songer et al. (U.S. Patent Publication Number 2003/0220691).

Songer et al. disclose the claimed invention except the anterior portion of the peripheral shock absorber being thicker than the posterior portion (claim 16). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Songer et al. where the anterior portion of each endplate and the peripheral shock absorber is thicker than the posterior portion, since it is just one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of making a device more beneficial for the user. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claim 11, i.e. "wherein the lordosis produces an angle between 5 and 20 degrees," it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Songer et al. where the lordosis produces an angle between 5 and 20 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Songer et al. (U.S. Patent Publication Number 2003/0220691) in view of Bryan (U.S. Patent 6,749,635). Songer et al. discloses the claimed invention except for a second articulating core member comprising a first articulation surface adapted for

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articulation with the first articulation of the first endplate and a second articulation surface adapted for articulation with the first articulation surface of the second endplate, and a second peripheral shock-absorbing component comprising a first surface contacting the first peripheral surface of the first endplate and a second surface contacting the second peripheral surface of the second endplate. Bryan discloses a motion disc device and teaches the use of more than one disc in order to achieve a full range of motion of the functional spinal unit and to have an increased cushion effect (see Column 3, lines 30-38). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Songer et al. with a second articulating core member comprising a first articulation surface adapted for articulation with the first articulation of the first endplate and a second articulation surface adapted for articulation with the first articulation surface of the second endplate, and a second peripheral shock-absorbing component comprising a first surface contacting the first peripheral surface of the first endplate and a second surface contacting the second peripheral surface of the second endplate, in view of Bryan, in order to achieve a full range of motion of the functional spinal unit and to have an increased cushion effect.

Response to Arguments

Applicant's arguments filed on September 14, 2005 have been fully considered, but they are not persuasive. In response to applicant's argument that Songer et al. does not teach or suggest that the elastic shock absorbing ring is tenaciously attached to the respective inner surface of each endplate, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is

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only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In other words, the elastic shock absorbing ring of *Songer et al.* is capable of being tenaciously attached to the respective inner surface of each endplate (see paragraph 0062, particularly lines 4-7). Moreover, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Examiner respectfully disagrees with applicant's argument that *Songer et al.* does not teach or suggest that the inner surface of each prosthetic endplate comprises a channel, since the inner surface of each prosthetic endplate does comprise a channel, wherein each peripheral surface of the shock-absorbing component is adapted to fit within the respective channel (see Figure 11F above). Furthermore, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO A. ROBERT
EXAMINER
PRIMARY EXAMINER